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09/204,236	12/03/1998	GREGORY S. HAMILTON	AR218-X	5251

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EXAMINER

CHANG, CELIA C

ART UNIT	PAPER NUMBER
1625	

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Please find below and/or attached an Office communication concerning this application or proceeding.



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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Paper No. 36

Application Number: 09/204,236

Filing Date: December 3, 1998

Appellant(s): Gregory S. Hamilton et al.

MAILED
OCT 24 2002
GROUP 2900

Rouget F. Henschel

For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed October 1, 2002.

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(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement of no related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief. However, the Appeals of SN 09/204,238 are of the same nature and issues.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

Appellant's brief includes a statement that claims 90-111 stand or fall together.

(8) *ClaimsAppealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

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(9) *Prior Art of Record*

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

WO 00/16603 Li, Jia-He et al. 03-2000

WO 99/14998 Magal et al. 04-1999

Feghali et al. "Mammalian auditory hair cell regeneration/repair and protection: a view and future directions
MEDLINE 1998242495 (1998)

(10) *Grounds of Rejection*

The following ground(s) of rejection are applicable to the appealed claims:

The rejection of claims 90-107 under the judicially created doctrine of obviousness-type double patenting as set forth in prior Office Action, Paper No.26. is now applicable to all the pending claims.

Claims 90-111 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over copending claims 1-177 of copending application No. 09/159,105 or continuation/divisional thereof in view of Feghali et al. Claims 1-177 of SN 09/159,105 (see WO 99/14998 of 1449) are drawn to treatment of neurological disorder i.e. treatable by neurotrophic factors of the instant claims, broadly also included the sensorineurotrophic hearing loss which is one of the neurological disorders generically embraced by the instant claims as evidence by Feghali that sensorineural hearing loss is a neurological disorder treatable by neurotrophic factors. In the instant case, the neurotrophic factors of SN 09/159,105 generically embraced the instantly claimed compounds.

In the advisory action, a later filed WO 00/16603 which fully incorporated SN 09/159,105 was evidenced to be filed by Guilford Pharmaceuticals.

(11) *Response to Argument*

Initially, some factual situation which has been made of record needs to be clarified by Appellants before any decision on propriety of a provisional “double patenting” can be assessed.

It is noted in the record that:

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Instant application

SN 09/204,236 Filing date 12/03/98,

Priority date: 60/087,842 06/03/98

Inventor: Hamilton, Norman, Wu

Assignee: Guilford Pharmaceuticals, Inc./GPI NIL Holdings, Inc.;
AMGEN, Inc.

Claimed scope, subgeneric to SN 09/159,105, compounds and methods fully embraced by claims of SN 09/159,105

Copending application

SN 09/159,105, not yet issued, Filing date, 09/12/98
(see WO 99/14998 submitted on 1449)

Priority date: 60/059,905 09/24/97
60/059,963 09/25/97

Inventor: Magal

Assignee: AMGEN, Inc.

Claimed scope, generic to a group of Markush compounds and method of treating neurological disorders using such, embraced all the compounds and method of **instant application**.

Evidential application, WO 00/16603

SN 09/159,105, not yet issued, Filing date, 09/12/98
(see WO 00/16603)

Priority date: 60/101,007 09/18/98

Inventor: Li, Hamilton, Steiner

Assignee: Guilford Pharmaceuticals, Inc.
AMGEN, Inc.

Claimed scope, **identical** to WO 99/14998 i.e. generic to a group of Markush compounds and method of treating neurological disorders using such, embraced all the compounds and method of **instant application**.

Please note that the rejection of obviousness type double patenting was a “provisional” rejection and under the instruction of MPEP §804, a provisional obviousness type double patenting can be withdrawn to let one set of claims becomes allowable “were the application is the *first* of the two copending cases”. In making such decision, the above record, made it impossible to decide *who* owns *what* at *when* because these evidence of record showed that both Guilford and Amgen and three sets of inventors continuously filed claims of the same or subgeneric subject matter. Such evidence indicated a case of “unjustified timewise extension of the right to exclude granted by a patent no matter how the extension is brought about”.

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Unless Appellants can provide “evidence” and claims wherein clear lines of demarcation together with clear identification of time of invention being made by clearly differentiated inventive entities/assignees, the obviousness double patenting should be maintained to ***prevent unjustified timewise extension of the right to exclude granted by a patent no matter how the extension is brought about.***

These evidence recited above clearly answered the arguments recited by Appellants on page 4 wherein Appellants demand that “The examiner *[has not]* should provide substantial evidence that the ‘105 application is an application filed by the “same inventive entity or by different inventive entities having a common invention, and/or by a common assignee”. Please note that at least at the time the invention was made i.e. the provisional filing, both the instant claims and the SN 159,105 claims are owned by *a* common assignee, Amagen, Inc.(see assignment registered by Appellants). Again, the Examiner reiterates that it is Appellants responsibility to show *who* owns *what* at *when*; and, based on such evidence submitted, to provide claims wherein clear lines of demarcation together with clear identification of time of invention being made by clearly differentiated inventive entities/assignees to ***prevent unjustified timewise extension of the right to exclude granted by a patent no matter how the extension is brought about.***

With respect to Appellants’ argument (p.3 of brief) that the Examiner has based the obviousness conclusion exclusively on the genus-species relationship between the claims of the ‘105 application and the present claims in doing so the Examiner has applied a *peer se* rule in clear violation of the relevant USPTO guidelines and case law citing MPEP §2144.08.II *In re Baird*, 29 USPQ2d 1550.

The Examiner’s position is

It has been clearly explained that the copending claims *fully* embraced the instant claims.

The requested *In re Baird* analysis argued by Appellants i.e. p.3 brief, has been clearly done when the rejection was delineated in Paper No. 26 as recited supra. The newly submitted claims 90-96 are subgenus of claims 1-177 of SN 09/159,105 while all the compounds of these newly submitted claims are encompassed by the copending claims. Specifically, all the compounds including those structures of claims 90-111 are found in Table L pages 243-248. Therefore, contrary to Appellants allegation, that the newly submitted

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claims are "...species or subgenus is encompassed by the [prior art] genus is not sufficient by itself to establish a prima facie case of obviousness"; the instantly claimed subgenus is a claim to "all the preferred sulfonyl pyrrolidine compounds disclosed and encompassed by the copending claims". Please note that one skilled in the art does not have to pick or choose with any motivation since every single sulfonyl pyrrolidine of the instant claims *is* encompassed by the claims of SN 09/159,105. In the instant situation, a prima facie case of analysis has been made by Appellants claims since *all* the preferred embodiments of the copending claims have been placed in the instant set of claims. The question is why would one having ordinary skill in the art "**not**" to "pick and choose" "all" the preferred compounds for the claimed method? Appellants' argument is totally inappropriate with respect to the Baird situation since there is absolutely no picking and choosing required. The copending claims have completely incorporated *all* of the newly submitted claims and the newly submitted claims encompassed the *whole* preferred embodiment i.e. Table L supporting the copending claims.

On the contrary, applying the well understood doctrine of anticipation wherein a species anticipates a genus, the complete set of claims 90-111 anticipates claims 60-66 since every single species of the instant claims is embraced by the copending claims guided by the explicit examples of Table L p.243-248.

Further, it was clearly studied and observed that the broad genus, supported by the description of the copending specification, differ from the instant claims with the disorder of the sensorineuropathic hearing loss, for which the instant specification did not have antecedent basis. It has been provided to Appellants that sensorineuropathic hearing loss is a well recognized disorder of the neurological nature treatable by neurotrophic agents such as encompassed by the newly submitted claims.

Even if one gives credit to Appellants argument that the copending claims and the newly submitted claims are *mere* species and genus relationship, the instant situation compared to In re Kaplan as recited MPEP 804.I.C. would clearly place the obviousness rejection based on preventing unjustified timewise extension of right to exclude granted by a patent proper.

Please note that In re Kaplan documented that at least one inventor was involved in the parent application with a co-inventor of a species of the genus in the parent case. Contrary to Kaplan, the instant species were filed by a set of completely different inventors (Hamilton, Norman, Wu) and none were in the SN 09/159,105 (Magal) case. However, since one common assignee was registered for both applications and

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the claims are obvious variation, not identical, it is appropriate to reject the claims under obviousness type double patenting.

Conclusion

Based on evidence in the record, it is proper to rejection the newly submitted claims under the judicially created doctrine of obviousness type double patenting to *prevent unjustified timewise extension of the right to exclude granted by a patent no matter how the extension is brought about*, and it is Appellants' responsibility to resolve the issues of *who* owns *what* at *when*, and, to provide claims wherein clear lines of demarcation are made based on such evidence submitted by Appellants of time, subject matter and clear identification of differentiated inventive entities/assignees.

For the above reasons, it is believed that the rejections should be sustained.



Conferees



Alan L. Rotman, SPE 1625

Respectfully submitted,
Celia Chang
Primary Examiner
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Joseph K. McKane, SPE 1626